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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,370	02/19/2002	Marc Alizon	2356-0011-10	2811

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EXAMINER	
PARKIN, JEFFREY S	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 04/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,370	ALIZON ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-28 and 31-50* is/are pending in the application.

4a) Of the above claim(s) *40-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-28 and 31-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the amendment filed 09 December, 2004. Claims 27, 28, 31, 32, and 33 were amended and new claims 40-50 introduced. Newly submitted claims 40-50 are directed to an invention that is independent or distinct from the invention originally claimed. The claims are directed toward invariant peptide sequences whereas the originally presented claims are directed toward peptidic variants. Each of the identified groups contains structurally and functionally different polypeptides. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 40-50 are withdrawn from further consideration as being directed towards a nonelected invention (refer to 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03). Claims 23-28 and 31-39 are currently under examination.

35 U.S.C. § 112, Second Paragraph

The previous rejection of claims 27, 28, 32, and 33 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is hereby withdrawn in response to applicants' amendment.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it

is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-28 and 31-39 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). Claims 23-26 and 31 are directed toward immunogenic HIV-1 Env polypeptides of 5-150 aa comprising at least one amino acid substitution at a specified position (e.g., aa 8, 9, 90, etc.). Claims 27, 28, 32, and 33 are directed toward methodologies that require these peptides. Claims 34-39 are also directed toward immunogenic HIV-1 Env polypeptides comprising one of the aforementioned substitutions and include additional limitations pertaining to the overall peptide length (e.g., 21 aa, 43 aa, 79 aa, etc.).

As previously set forth, in order to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had **possession** of the claimed invention. See, e.g., *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. The issue raised in this application is whether the original application provides adequate support for the broadly claimed genus of **immunogenic polypeptide fragments** comprising **HIV-1_{MAL} epitopes** of **5-150 amino acid residues** wherein **at least one amino acid residue is substituted at one of the specified positions**. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures,

figures, diagrams, and formulas that **fully set forth the claimed invention**. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. **A biomolecule sequence (e.g., epitope) described only by functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest.** *In re Bell*, 991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this decision that **a laundry list disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art to any particular species.**

An applicant may show possession of an invention by disclosure of drawings or **structural chemical formulas** that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or

partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of identifying characteristics include a nucleotide or **amino acid sequence**, chemical structure, **binding affinity**, **binding specificity**, and molecular weight. The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. Without such a correlation, the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In the latter case, **disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement**. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). *In re Wilder*, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

As previously noted, perusal of the disclosure reveals the cloning and characterization of a novel human immunodeficiency virus type 1 originally designated lymphadenopathy associated virus (LAV) MAL, or LAV_{MAL}. A proviral molecular clone was obtained and complete nucleotide isolate of this sequence ascertained (see Figs. 7A-7I). The deduced amino acid sequences of the various viral structural and non-structural genes were also set forth in Figure 7. Specific envelope polypeptide fragments were set forth on p. 36

of the specification (e.g., 1-530, 34-530, 531-877, 680-700, 37-130, 211-289, 488-530, and 490-620). It should be noted that these designations actually referenced LAV_{BRU} amino acid sequences, not specific LAV_{MAL} polypeptides. Thus, the skilled artisan might conclude that applicants contemplated making and using these specific envelope polypeptides. However, the skilled artisan would not reasonably conclude that applicants were in possession of the claimed invention.

First, **the disclosure fails to identify specific HIV-1_{MAL} immunogenic fragments of the claimed lengths and substitutions.** The specification only sets forth the deduced amino acid sequences of the full-length non-structural and structural genes as set forth in Figure 7 and the specific Env fragments set forth on p. 36. Figure 3 also fails to identify immunogenic MAL peptides. This figure simply provides an amino acid comparison between MAL, BRU, ARV-2, and ELI to assess their genetic relatedness. The figure does not identify or lead the skilled artisan to any particular immunogenic fragment, particularly one carrying amino acid substitutions. Second, **the disclosure fails to perform any type of comparison wherein specific immunogenic fragments from isolate MAL are identified and acceptable amino acid substitutions are performed.** It is well-known in the art that subtle perturbations in an amino acid sequence can profoundly affect both the immunogenic and antigenic properties of any given polypeptide. Thus, the skilled artisan can only hazard a guess as to which substituted MAL fragments will remain immunogenic. Third, **the disclosure fails to provide adequate support for MAL-specific polypeptides the recited lengths (e.g., 21, 43, 79, 94, and 131 aa).** The only numerical limitations set forth in the disclosure recite immunogenic polypeptides or fusion proteins which may contain between 5 and 150 amino acids (see p. 28). Thus, support does not exist for the current size limitations. Nothing in the

disclosure directs the skilled artisan toward any particular MAL immunogenic fragment or any fragment carrying amino acid substitutions. The disclosure fails to identify those molecular determinants modulating the immunogenicity of any given polypeptide fragment. Clearly, the claimed invention simply represents an attempt by applicants to capture subject matter which was neither described nor contemplated at the time of filing. Accordingly, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing.

Response to Arguments

Applicants again traverse and submit that support for the claimed substitutions can be found in Figure 3. Applicants further reference pages 16 and 23 in support. The examiner still does not concur with this assessment. Figure 3 provides the amino acid sequence alignment of four different HIV-1 isolates (e.g., BRU, ARV-2, MAL, and ELI). The purpose of this figure is to simply illustrate that while these are all HIV-1 isolates, nevertheless, they display considerable genetic diversity in the envelope region. Pages 16 and 23 also fail to provide support for the claimed invention. None of these pages sets forth any particular peptidic variants as currently claimed.

Applicants further assert that consideration of *Enzo Biochem, Inc.* v. *Gen-Probe, Inc.*, 323 F.3d 956 (Fed. Cir. 2002), is warranted. Applicants argue that the fact pattern is similar in both situations. It was noted that sufficient structural and functional information was provided in the specification. The examiner does not concur with this assessment. The problem with the current claims is that the skilled artisan would reasonably conclude that applicants were not in **possession** of the claimed invention. Nothing in the disclosure leads the skilled artisan to a polypeptide with one or more of the recited amino acid

substitutions. A more relevant piece of case law might be University of Rochester v. G.D. Searle & Co., 69 U.S.P.Q.2d 1886 (C.A.F.C. 2004). Here the court in discussing *In re Ruschig*, 379 F.2d 990 [154 U.S.P.Q. 118] (C.C.P.A. 1967), noted that although a particular compound fell within the scope of the originally filed claim, nevertheless, "it was never named or otherwise exemplified in the appellants original patent application." These facts are similar to those in the instant application wherein the applicants have failed to clearly identify or set forth any of the specific peptidic variants currently being claimed. As the Supreme court has previously cautioned, "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Brenner* v. *Manson*, 383 U.S. 519, 536 [148 U.S.P.Q. 689] (1966). Accordingly, the rejection is proper and hereby maintained.

Finality of Office Action

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). **A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.**

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, James C. Housel, can be reached at (571) 272-0902. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Formal communications may be submitted through the official facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington, VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

15 April, 2005